

Notice of Allowability

Application No.

09/689,136

Examiner

Daniel M. Sullivan

Applicant(s)

ENGELHARDT ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 20 May 2005.
2. ☒ The allowed claim(s) is/are 1-4,6-12,29-84 and 86-95.
3. ☒ The drawings filed on 02 December 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>5/20/05, 8/1/05</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Janet Embretson on 30 August 2005.

The application has been amended as follows:

In the claims

10. (Currently Amended) The method of claim 1 or 87 wherein the ~~virus~~-AAV is recombinant AAV.

11. (Currently Amended) The method of claim 10 wherein the recombinant ~~virus~~-AAV encodes a therapeutic peptide or polypeptide.

12. (Currently Amended) The method of claim 10 wherein the recombinant ~~virus~~-AAV comprises a marker gene that is detectable or selectable.

83. (Currently Amended) The method of claim 1 or 87 further comprising contacting the mammalian cell with a second agent that enhances the an activity of the agent contacted with the mammalian cell.

The following is an examiner's statement of reasons for allowance:

Election/Restrictions

Linking claim 1 is allowed. Since the restriction requirement between inventions I-IV, as set forth in the Office action mailed on 11 October 2001, was conditioned on the nonallowance of the linking claim (as was acknowledged in response to Applicant's traverse of the restriction requirement in the Office Action mailed 26 June 2002), **the restriction requirement as to the linked inventions is hereby withdrawn**. Claims 37-82, previously withdrawn from consideration as a result of the restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. It is noted that the amendment filed 3 August 2005 incorrectly identifies claims 37, 47 and 79 as "Currently Amended" instead of "Withdrawn" or "Withdrawn, Currently Amended"; however, this issue is moot in view of the rejoinder of the claims. In view of the withdrawal of the restriction requirement as to the linked inventions, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Response to Amendment

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Claim Rejections - 35 USC § 112

Rejection of claims 1-12, 29-36, 83, 84, 86 and 88 under 35 U.S.C. 112, first paragraph, as encompassing new matter because the originally filed disclosure fails to disclose a method wherein a cell is not contacted with an agent and an AAV is **withdrawn** in view of the amendment of claims 1 and 88 to recite the step of “providing a mammalian cell contacted with an agent and AAV”.

Rejection of claims 88 and 89 under 35 U.S.C. 112, first paragraph, as encompassing new matter by reciting the agent identified enhances “internalized” AAV transport to the nucleus of the contacted mammalian cell is **withdrawn** in view of Applicant’s arguments and further in view of the teachings bridging pages 77-78 of the specification, which describe assays wherein the intracellular distribution of AAV was determined. It is noted that in the Remarks traversing this rejection, Applicant refers to a supporting statement at “page 77, line 6” of the specification. It appears that this is a typographical error and applicant is actually referring to page 78, line 6.

Claim Rejections - 35 USC § 102

Rejection of claims 1, 4-12, 29-36 and 88 under 35 U.S.C. 102(b) as being anticipated by Nair *et al.* (1998) US Patent No. 5,831,068 is **withdrawn** in view of the amendments to claims 1 and 88 such that the method comprises providing a mammalian cell contacted with an agent and AAV.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636


DANIEL M. SULLIVAN
PATENT EXAMINER